UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,096	02/01/2001	Dan Nilsson	54337.000009	6906

21967 7590 09/15/2009

HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER	
STEADMAN, DAVID J	
ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
09/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/720,096	NILSSON ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2005 and 01 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9-12,17,24 and 28-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9-12,17,24,28,30-34,36-39 and 41* is/are rejected.

7)☒ Claim(s) *29,35 and 40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 1, 9-12, 17, 24, and 28-41 are pending in the application.

[2] Applicants' amendment to the claims, filed on 7/1/09, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[3] Receipt of information disclosure statements, filed on 3/2/05, 8/28/06, 6/23/09, is acknowledged.

[4] Receipt of a sequence listing in computer readable form (CRF), a paper copy thereof, a statement of their sameness, and a statement that no new matter has been added to the specification by the paper copy of the sequence CRF, all filed on 1/4/08, is acknowledged.

[5] Applicant's remarks filed on 6/6/05 in response to the Office action mailed on 10/1/04 have been fully considered and are deemed to be persuasive to overcome at least one of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Rejections and/or objections previously applied to claims 13-14 and 26-27 are withdrawn solely in view of the instant claim amendment that cancels these claims.

[6] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Specification/Informalities

[7] In the remarks filed on 6/6/05, applicant notes that the subject matter of claim 12, *i.e.,* the sequences of SEQ ID NO:7, 8, 9, 10, and 11, are fully supported by reference WO 98/10089, which, according to applicant "is incorporated by reference at page 11 of the specification". However, the examiner can find no such incorporation by reference statement at p. 11 of the specification and as such, the sequence listing filed on 1/4/08 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. It is suggested that applicant point to an appropriate incorporation by reference statement for WO 98/10089 in the specification as filed.

[8] In order to perfect the requirements for a sequence listing, applicant is required to submit an amendment to the specification directing entry of the sequence listing filed on 10/4/08 into the application.

Claim Objections

[9] Claim 29 is newly objected to in the recitation of "DSN12891", where it appears that applicant intends for the noted phrase to read "DSM 12891". See, *e.g.,* original claim 5 and specification at p. 19, lines 6-10.

Claim Rejections - 35 USC § 112, Second Paragraph

[10] The rejection of claims 1, 9-12, 17, 24, and 28-32 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the instant claim amendment.

Claim Rejections - 35 USC § 112, First Paragraph

[11] The written description rejection of claims 12-14 and 17 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the instant claim amendment.

[12] The scope of enablement rejection of claims 1, 9-12, 17, 24, and 28-32 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the instant claim amendment.

[13] Claim 12 is newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

MPEP § 2163.II.A.3.(b) states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description". According to MPEP § 2163.I.B, "While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure" and "The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that,

as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc.*, 935 F.2d at 1563-64, 19 USPQ2d at 1117".

In the remarks filed on 6/6/05, applicant notes that the subject matter of claim 12, *i.e.,* the sequences of SEQ ID NO:7, 8, 9, 10, and 11, are fully supported by reference WO 98/10089, which, according to applicant "is incorporated by reference at page 11 of the specification". However, the examiner can find no such incorporation by reference statement at p. 11 of the specification and as such, the sequence of SEQ ID NO:7 is considered to be new matter. It is suggested that applicant point to an appropriate incorporation by reference statement for WO 98/10089 in the specification as filed. If applicant can point to no such statement in the specification, applicant is encouraged to contact the examiner at the telephone number provided below.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[14] Claims 1, 9-10, 17, 24, 30, 33, 36-37, and 41 are newly rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dickely et al. (US Patent 5,691,185; cited as reference A in the Form PTO-892 mailed on 3/27/02; hereafter "Dickely") as evidenced by Groboillot et al. (*Biotechnol. Bioengineer.* 42:1157-1163, 1993; hereafter "Groboillot"). See MPEP 2112.III regarding a rejection under 35 U.S.C. 102/103. See MPEP 2131.01 regarding a multiple reference 35 U.S.C. 102 rejection.

Dickely teaches isolation of a purine auxotroph of *Lactococcus lactis* strain, DN209/pFDi19 (column 27, lines 1-42) and teaches milk is a medium that does not contain nucleotide precursors in amounts sufficient for growth of purine auxotrophs (column 11, lines 52-54). Dickely teaches a method of culturing the DN209/pFDi19 strain in milk, noting that the DN209/pFDi19 strain is unable to grow in milk not containing a purine source (column 27, lines 49-60). This anticipates claims 1, 9-10, 17, 24, 30, 33, 36-37, and 41 as written.

Regarding the limitations of "keeping the milk under conditions where the bacterial culture is able to acidify the milk" and "keeping the milk under conditions where the purine or thymidine auxotrophic bacterial strain is able to ferment the milk" in claims 1 and 30 respectively, although the reference of Dickely does not expressly teach that culturing the DN209/pFDi19 strain in milk results in acidifying or fermenting of the milk, this would have been a necessary result of the above described method of Dickely.

Regarding the limitation of "the purine or thymidine auxotrophic bacterial strain is a strain that increases the size of its cells without mitosis when cultured in milk" in claim 17, based on the specification disclosure at p. 12, lines 11-17, this would appear to be a necessary characteristic of the purine auxotrophic DN209/pFDi19 strain of Dickely.

Regarding the limitation of "whereby the milk is acidified to a pH less than or equal to 5.0" in claims 36 and 41, according to the specification, a purine auxotrophic strain of *Lactococcus lactis* present in the same medium as that of Dickely "was able to acidify milk at least to pH 5.0" (p. 17, lines 18-19). Because the generation time for *Lactococcus lactis* in milk is over 1 hour as evidenced by Groboillot at p. 1162, column 1, bottom, by culturing the DN209/pFDi19 strain of Dickely for 100 generations, it is the examiner's position that after 100 generations of DN209/pFDi19 strain, the milk would have been acidified at least to a pH of 5.0.

Since the Office does not have the facilities for examining and comparing applicants' method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (*e.g.,* that the method of the prior art does not result in acidifying or fermenting milk). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald* et al., 205 USPQ 594.

[15] Claim(s) 31 and 38 are newly rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dickely as

evidenced by Luksas (US Patent 3,720,520; hereafter "Luksas"). See MPEP 2131.01 regarding a multiple reference 35 U.S.C. 102 rejection.

The relevant teachings of Dickely are set forth above. While Dickely does not characterize milk as a product for cheese flavoring, evidentiary reference Luksas acknowledges that milk is considered to be a product for cheese flavoring (column 2, lines 23-30). This anticipates claim 31 as written.

Regarding the limitation of "maintaining the thus-obtained inoculated dairy flavouring and/or product for cheese flavouring starting material under such conditions that the bacterial strain of the bacterial culture is metabolically active" in claim 31, this would appear to be a necessary characteristic of the purine auxotrophic DN209/pFDi19 strain of Dickely.

Since the Office does not have the facilities for examining and comparing applicants' method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (*e.g.,* that the method of the prior art does not result in acidifying or fermenting milk). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald* et al., 205 USPQ 594.

Claim Rejections - 35 USC § 103

[16] Claim(s) 11, 34, and 39 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Dickely (*supra*) in view of Barach et al. (US Patent 4,294,930; cited

as reference B in the Form PTO-892 mailed on 3/27/02; hereafter "Barach") and as evidenced by Luksas (*supra*).

The relevant teachings of Dickely are set forth above. Dickely does not specifically teach the concentration of the culture of the DN209/pFDi19 strain added to milk.

Barach teaches that when culturing a microbe in milk, it is desirable to use 10^8 CFU/mL (column 1, lines 14-19).

At the time of the invention it would have been obvious to one of ordinary skill in the art to combine the teachings of Dickely and Barach to propagate the DN209/pFDi19 strain in a medium comprising purine and use 10^8 CFU/mL of the culture of the DN209/pFDi19 strain in the method of Dickely. One would have been motivated to use 10^8 CFU/mL of the culture of the DN209/pFDi19 strain in the method of Dickely because Barach teaches this is desirable. One would have been motivated to propagate the DN209/pFDi19 strain in a medium comprising purine in order to achieve 10^8 CFU/mL of the culture. One would have had a reasonable expectation of success to propagate the DN209/pFDi19 strain in a medium comprising purine and to use 10^8 CFU/mL of the culture of the DN209/pFDi19 strain in the method of Dickely because of the results of Dickely and Barach. Therefore, the method of claims 11 and 34 would have been obvious to one of ordinary skill in the art at the time of the invention.

[17] Claim 28 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over Dickely (*supra*) in view of Nilsson et al. (*Mol. Gen. Genet.* 235:359-364, 1992; cited as reference 7 in the IDS filed on 10/9/03; hereafter "Nilsson").

The relevant teachings of Dickely are set forth above. Dickely does not teach or suggest screening for purine auxotrophy of a culture of DN105 using milk.

Nilsson teaches purine auxotrophic mutants of *L. lactis,* including strain DN105 (p. 360, column 2, bottom). Nilsson does not teach milk as a purine auxotroph selection medium.

At the time of the invention it would have been obvious to one of ordinary skill in the art to combine the teachings of Dickely and Nilsson to culture DN105 in milk. One would have been motivated to do this because Dickely teaches milk lacks purines and is a medium for screening for purine auxotrophy. One would have had a reasonable expectation of success to culture DN105 in milk because of the results of Dickely and Nilsson. Therefore, the method of claim 28 would have been obvious to one of ordinary skill in the art at the time of the invention.

[18] Claim 32 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over Dickely (*supra*) in view of Jochimsen et al. (*Mol. Gen. Genet.* 143:85-91, 1975; hereafter "Jochimsen").

The relevant teachings of Dickely are set forth above. Dickely does not teach or suggest screening for purine auxotrophy of a culture of *E. coli* using milk.

Jochimsen teaches selecting *E. coli* purine auxotrophs (*e.g.,* p. 88, column 1). Jochimsen does not teach milk as a selection medium.

At the time of the invention it would have been obvious to one of ordinary skill in the art to combine the teachings of Dickely and Jochimsen to select *E. coli* purine auxotrophs using milk as a selection medium. One would have been motivated to do this because Dickely teaches milk lacks purines and is a medium for screening purine auxotrophy. One would have had a reasonable expectation of success to select *E. coli* purine auxotrophs using milk as a selection medium because of the results of Dickely and Jochimsen. Therefore, the method of claim 32 would have been obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

[19] Status of the claims:

- Claims 1, 9-12, 17, 24, and 28-41 are pending.
- Claims 1, 9-12, 17, 24, 28, 30-34, 36-39, and 41 are rejected.
- Claims 29, 35, and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- Claims 35 and 40 appear to be free of the prior art of record because there is no evidence that the milk of the reference of Dickely contained a bacteriophage and the examiner can find no teaching or suggestion to modify the method of Dickely to use milk with a bacteriophage.

- Claim 29 appears to be free of the prior art of record because the examiner can find no teaching or suggestion of the *L. lactis* strain MBP71.

- Claim 12 appears to be free of the prior art of record because the examiner can find no teaching or suggestion to add to milk a purine or thymidine auxotrophic bacterial strain transformed with a plasmid comprising SEQ ID NO:7.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David J. Steadman/
Primary Examiner, Art Unit 1656